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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,411	09/01/2006	Irina Nikolaievna Kuznetsova	VO-775	2526

42419 7590 08/11/2009

PAULEY PETERSEN & ERICKSON
2800 WEST HIGGINS ROAD
SUITE 365
HOFFMAN ESTATES, IL 60169

EXAMINER	
PIHONAK, SARAH	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
08/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,411	KUZNETSOVA ET AL.	
	Examiner	Art Unit	
	SARAH PIHONAK	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) *17-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-16 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/2008,9/10/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/RU05/00058, filed on 2/7/2005.

Priority

This application was filed on 9/1/2006, and is a national stage application of PCT/RU05/00058, filed on 2/7/2005. This application also claims foreign priority to Application No. 2004106722, filed on 3/1/2004. A certified copy of the foreign priority application has been received. An English translation of English abstract of the foreign priority application is respectfully requested. The effective filing date and U.S. priority date given to the instant claims is 2/7/2005.

Response to Restriction Requirement

1. Applicant's election with traverse of Group I, claims 1-16, 22, and 23 in the reply filed on 5/19/2009 is acknowledged. The traversal is on the ground(s) that the instant claims do not lack unity of invention over the prior art. This is not found persuasive because the US 6,113,919 patent discloses an oxygen carrier (i.e. blood substitute products) comprised of at least one perfluorocarbon, as well as mixtures of perfluorocarbons, such as perfluorodecalin, perflubron (perfluorooctylbromide), and trisubstituted amines of perfluorocarbons (Abstract; column 8, line 64-column 9, line 20). The US '919 patent also discloses emulsion preparation of the perfluorocarbons, as well as phospholipids as a surfactant (column 9, lines 21-29). The instant claims are also drawn to a perfluorocarbon emulsion comprised of mixtures of perfluorocarbons such as

perfluorodecalin, perfluorooctylbromide, and perfluorinated tertiary amines, with a phospholipid surfactant. Therefore, the instant claims do not represent a contribution over the prior art. The Applicant has also argued that the International Searching Authority found the instant claims to have unity of invention, as well as novelty and inventive step. This argument has been fully considered, as well as the report issued by the International Searching Authority. However, an independent analysis of any possible prior art was required and was made by the examiner.

In the reply filed on 1/23/2009, and the reply filed on 5/19/2009, the Applicants had traversed the species election requirement which had been issued in the office action dated 12/19/2008. In reviewing the instant claims, the examiner agrees to withdraw the election of species requirement.

The restriction requirement is still deemed proper and is therefore made FINAL.

2. In the reply filed on 1/23/2009, the Applicants cancelled claims 1 and 21, and added claims 24 and 25, which are directed to a product. Entry of new claims 24-25 is allowed, as they do not constitute new matter.

3. Claims 17-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

4. The Applicants are reminded that, in the event that the product claims are found allowable, rejoinder of the product claims with the process claims will be considered.

5. Claims 2-16, and 22-25 were examined.

6. Claims 2-16 and 22-25 are rejected.

Claim Rejections-35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 2-4, 7-8, 22, and 24-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Vorobyev, RU 2162692 patent publication. The reference of Vorobyev was presented in the Information Disclosure Statement. For convenience, an English translation of the reference was used for this rejection.

9. The instant claims are drawn to a fluorocarbon emulsion comprised of perfluorocarbon compounds perfluorodecaline and perfluorooctylbromide in a ratio between 10:1 and 1:10, in a salt-water medium, with a phospholipid emulsifier, and a mixture of perfluorinated tertiary amines, such as perfluoro-N-methylcyclohexylpiperidine and perfluorotributylamine. The instant claims are also drawn to the composition comprising 2-40% by volume fluorocarbon compounds, and 1-50% of a total content of rapidly eliminated fluorocarbon compounds.

10. Vorobyev discloses a perfluorocarbon emulsion comprised of a mixture of the compounds perfluorodecaline (PFD), perfluorooctylbromide (PFOB), and perfluoromethyl cyclohexyl piperidine(PFMCP), and perfluorotributyl amine (PFTBA) (p. 6, first full paragraph, English translation). Vorobyev teaches that perfluorodecaline and perfluorooctylbromide are rapidly eliminated biologically, while perfluoromethyl

cyclohexyl piperidine and perfluorotributyl amine is retained for a longer period of time in biological fluids and tissues (p. 2, second paragraph-p. 3, top paragraph). Vorobyev teaches a salt-water medium emulsion (p. 6, second paragraph) and that the ratio of perfluorodecaline: perfluorooctylbromide is from 1:1 to 10:10, which is within the range instantly claimed (p. 6, second paragraph). Phospholipid emulsifiers are also present (p. 12, claim 1), and it is taught that phospholipids from egg yolk and soy are known in the art (p. 3, first full paragraph). It is taught that the phospholipid component is present from 0.4-4.8 % (p. 7, top sentence). While the proxanol compound is presented in this example, it is taught that proxanol and phospholipids are equivalent stabilizers (p. 12, claim 1). Perfluorocarbons are disclosed as being present from 1-20% (p. 7, top sentence). Ratios of rapidly eliminated perfluorocarbons: slowly eliminating perfluorocarbons are taught as being present in a ratio of 2:1, or 10:1 (p. 8, Example 1, p. 9, Example 2). Therefore, in a composition comprised of 20% perfluorocarbons, in which the ratio of perfluorooctylbromide: perfluorodecaline: perfluoro-N-methylcyclohexyl piperidine is 10:2:1, the amount of rapidly eliminated compounds (perfluorooctylbromide and perfluorodecaline) present is at least 15% in the emulsion, which meets the limitations of claim 4. Therefore, Vorobyev anticipates the instant claims.

Claim Rejections-35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 9-13, 15-16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vorobyev, RU 2162692 patent publication, as applied to claims 2-4, 7-8, 22, and 24-25, in view of Ganong, Rev. of Medical Physiology, 17th ed., p. 221-222), and further in view of Trevino et. al., US 5,733,526 patent.

15. The rejection of claims 2-4, 7-8, 22, and 24-25 was discussed supra.

16. The instant claims are directed to a phospholipid emulsion comprised of a mixture of perfluorocarbons such as perfluorodecalin, perfluorooctyl bromide, and perfluoro-N-methylcyclohexylpiperidine, in a salt water medium, with adjuvant oils at a quantity of 1-15% of the total content of the phospholipids. The instant claims are also drawn to a fluorocarbon dispersion in which the mean particle size of the dispersion is in the range of 0.06-0.2 μm, and the emulsion has an osmotic pressure in the range of 100-300 mOsmol/L.

17. The teachings of Vorobyev as applied to the instant claims are discussed supra. Additionally, Vorobyev also teaches that the average particle size of the perfluorocarbon emulsion mixture is 0.05 μm (p. 10, Example 3, first full paragraph; p. 11, last paragraph, Example 5-p. 12, top two sentences). While Vorobyev does not explicitly teach that the average particle size of the perfluorocarbon emulsion is from 0.06-0.2 μm, the average particle size of 0.05 μm is very close to this range, especially to the particle size of 0.06 μm. It would have been considered routine and obvious for one of ordinary skill in the art to optimize particle size ranges based upon the teachings of the prior art. As Vorobyev teaches an average particle size which is very close to the size range instantly claimed, it would have been obvious for one of ordinary skill in the art to optimize the particle size range to 0.06-0.2 μm, as instantly claimed. Vorobyev does not explicitly teach that the osmotic pressure of the perfluorocarbon emulsion is in the range between 100-350 mosmol/L. However, it is known in the art that the osmolality of blood plasma is usually near 285 mosmol/L , as taught by Ganong (p. 222, right column, first full paragraph). The osmotic pressure of the instantly claimed perfluorocarbon emulsion

is within the range of normal blood plasma osmotic pressure. Therefore, it would have been obvious for one of ordinary skill in the art to establish an osmotic pressure range between 100-350 mosmol/L, as this range is within the normal physiological range for blood plasma.

Vorobyev does not explicitly teach that the perfluorocarbon emulsion further comprises adjuvant vegetable oils.

Trevino et. al. teaches a perfluorocarbon emulsion which also comprises at least one hydrocarbon oil, as well as dispersing agents (Abstract; column 4, lines 21-26). Trevino et. al. teaches that the emulsion is useful for delivering a wide variety of bioactive agents to patients, such as physiological gases (Abstract; column 7, lines 10-30). Trevino et. al. teaches that the hydrocarbon oils can be selected from soybean oil, sunflower oil, and other oils (column 4, lines 43-45; lines 65-67). It is taught that the hydrocarbon oils impart advantageous pharmaceutical properties to the emulsion, including enhanced stability and bioavailability (column 2, line 60-column 3, line 4; column 3, line 62-column 4, line 21). Phospholipids as emulsifiers are also taught (column 5, lines 33-36). Trevino teaches that the hydrocarbon oils comprise about 0.01-50 % of the emulsion, and the emulsifiers comprise between 0.01-20% of the emulsion (column 6, lines 4-10). Therefore, as the amount of hydrocarbon oil present can be 1%, and the amount of phospholipid (as emulsifier) present can be 10% of the emulsion; the adjuvant hydrocarbon oil is in a quantity between 1-15% of the phospholipid, which meets the limitation of claim 9. The addition of sugars as osmotic agents is also taught (column 15, lines 56-62). Trevino et. al. also teaches that *at least one* hydrocarbon oil is

present in the emulsion (column 4, lines 22-26), and lists a variety of different oils, such as soybean and sunflower oil, as well as other natural oils (column 4, lines 67-67). While ricinus oil is not explicitly taught, it is a natural oil, and Trevino et. al. teaches that other natural oils in addition to soybean and sunflower oils can be present. Therefore, it would have been obvious to one of ordinary skill in the art that mixtures of two or three oils can be used in the emulsion, as well as ricinus oil.

Vorobyev teaches that a perfluorocarbon emulsion comprised of mixtures of perfluorodecalin, perfluorooctyl bromide, perfluoro-N-methylcyclohexylpiperidine and phospholipid emulsifiers in a salt-water medium is an improved oxygen delivery carrier. Trevino et. al. teaches that the addition of hydrocarbon oils to perfluorocarbon emulsions provides increased stability and bioavailability. One of ordinary skill in the art would have been motivated to combine the perfluorocarbon emulsion taught by Vorobyev with hydrocarbon oils, because Vorobyev teaches that the emulsion comprised of mixtures of different perfluorocarbons is effective as an oxygen delivery agent and has improved properties over previous perfluorocarbon formulations, while Trevino teaches that hydrocarbon oils enhance the stability and bioavailability of perfluorocarbon emulsions. Therefore, one of ordinary skill in the art would have expected success in preparing a formulation comprised of these agents, as they are taught as being beneficial in perfluorocarbon emulsions for use as oxygen carrier agents, and for the delivery of bioactive agents, etc. Therefore, the instant claims would have been prima facie obvious to one of ordinary skill in the art at the time of the invention, in view of the prior art.

Claim Rejection-35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

21. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vorobyev, RU 2162692 patent publication, as applied to claims 2-4, 7-8, 22, and 24-25 above, and further in view of Roth et. al., US 5,344,393 patent.

22. The rejection of claims 2-4, 7-8, and 24-25 is discussed supra.

23. Claim 14 is directed to a perfluorocarbon emulsion comprised of perfluorodecalin, perfluorooctyl bromide, and perfluorinated tertiary amines in a salt-water medium, with sodium and potassium chlorides and phosphates, and mannitol in injection water.

24. Vorobyev teaches perfluorocarbon emulsions comprised of perfluorodecalin, perfluorooctyl bromide, and perfluorinated tertiary amines, in a salt-water medium, with phospholipids, and sodium and potassium chlorides, and phosphates (p. 6, paragraphs 1-2; p. 11, second full paragraph).

While Vorobyev teaches that sugars such as glucose are present in the emulsion (p. 9, first full paragraph), it is not explicitly taught that mannitol is present in the emulsion.

Roth et. al. teaches a perfluorocarbon emulsion for use as an intravenous oxygen carrier (column 4, lines 55-68). Roth et. al. teaches the perfluorocarbon emulsion as prepared in injection water, along with egg yolk phospholipids, sodium chloride and sodium phosphates (column 7, Formula I, lines 34-48). Roth et. al. also teaches the addition of mannitol to the emulsion as an osmotic agent, so that the emulsion is at physiological isotonicity (column 7, lines 14-21).

One of ordinary skill in the art would have been motivated, at the time of the invention, to formulate the perfluorocarbon emulsion taught by Vorobyev with mannitol as an osmotic agent, because Vorobyev teaches that the perfluorocarbon emulsion comprised of mixtures of different perfluorocarbons is effective as an oxygen delivery agent and has improved properties over previous perfluorocarbon formulations, and

Roth et. al. teaches that mannitol is commonly used as an osmotic agent in perfluorocarbon emulsions formulated as intravenous oxygen carriers, to enable the formulation to be at physiological isotonicity. Therefore, success would have been expected in adding mannitol to the perfluorocarbon emulsion taught by Vorobyev, as the mannitol is known in the art as an effective osmotic agent for pharmaceutical perfluorocarbon emulsions. The instant claim would have been prima facie obvious to one of ordinary skill in the art, at the time of the invention, over Vorobyev, in view of Roth et. al.

Claim Rejections-35 USC § 112

25. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

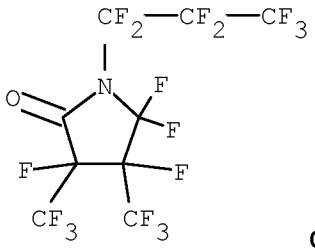
26. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

27. Claim 2 is drawn to the fluorocarbon emulsion according to claim 25, “further comprising 2-40% by volume fluorocarbon compounds". The terms “further comprising” impart indefinite language to the claim. It is not certain by the language if, in addition to the fluorocarbon compounds disclosed in claim 25, there is an addition of other fluorocarbon compounds which comprises 2-40% by volume of the emulsion, or, if the total amount of fluorocarbon compounds comprises 2-40% by volume of the emulsion.

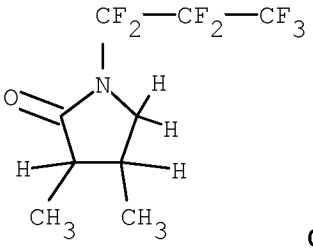
The claim was interpreted as, for prior art searching, that the total amount of fluorocarbon compounds present in the emulsion comprises 2-40% by volume of the emulsion. However, due to the indefinite language of this claim, it is not entirely certain what is meant, and clarification is requested.

28. Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

29. Instant claim 5 is directed to a perfluorocarbon emulsion according to claim 25, further comprising a mixture of tertiary amines such as cis and trans isomers of perfluoro-1-propyl-3,4-dimethylpyrrolidone. From the claim language, it is not certain if the compound present is the completely perfluorinated compound, which is shown as compound 1 below, or the compound 2 (shown below), where just the propyl group is perfluorinated.



compound 1



compound 2

Therefore, due to the indefiniteness of the claim, there is uncertainty regarding the invention that is being claimed. Applicants are respectfully requested to distinctly state which pyrrolidone compound is present in the emulsion, and also, to provide the source as to where the compound was obtained. If the compound was synthesized by the Applicants, the method of synthesis is requested. Claim 6, which is a dependent claim of claim 5, is also rejected for the reasons discussed.

Information Disclosure Statement

30. The information disclosure statements (IDS) submitted on 3/10/2008 and 9/10/2008 were filed. The following references on the IDS were not considered by the examiner: Periodical of the Russian Mendeleyev Chemistry Assoc., 1985, vol. 30, no. 4, p. 387-394; M.B. Bierkos, abridged dissertation, doctorate in medical science, Leningrad, 1991, p. 2-7; Biophysics, 1998, volume 33, no. 1, p. 126-129; I.N. Kusnezowa, abridged dissertation, doctorate in biological science, St. Petersburg, 1999, p. 2-7; Chemical-Pharmaceutical Periodical, 1987, no. 12, p. 1498-1503; Periodical for Physical Chemistry, 1993, volume 67, no. 9, p. 1884-1888; E.I. Majewskij, abridged dissertation, doctorate in medical science, Moscow, 1998, p. 2-5; RU 797546 patent

document. These references were not in English, did not have an English abstract, or were not accompanied by an explanation of their relevance to the instant invention (as the references were not in the English language). All other references listed on the IDS were considered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617